REMARKS

Applicants note that all amendments and cancellations of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),[1] and without waiving the right to prosecute the amended or cancelled Claims (or similar Claims) in the future.

In the Office Action mailed 9/23/09, the Examiner object to the brief description of the drawings for lacking a reference to Figures 7A and 7B. The applicants have amended the brief description of the drawings to include a description of Figures 7A and B. Support for this amendment can be found, for example, in Example 3 of the specification. As such, the applicants respectfully request that the objection be withdrawn.

In the Office Action mailed 9/23/09, the Examiner rejects Claims 3-7 under 35 U.S.C. 103(a) as allegedly obvious in light of Jeney et al (WO 03/07667; hereinafter Jeney) in view of NCBI Accession No. M14119 or Accession No. K02718 or Accession No. AY262282 or Accession No. J043553 and further in view of Lowe et al. (Nucleic Acids Research, 18:1757, 1990; hereinafter Lowe). The applicants respectfully disagree with the rejection. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the amended claims (or similar claims) in the future, the Applicants have amended Claim 3 to recite that each of the disclosed primer pairs are utilized, the primer pairs specifically amplify specific regions of the L1 gene of each of the human papillomavirus (HPV) genotypes HPV 11, HPV 16, HPV 18 and HPV 31, and the primers specifically and selectively amplify each of the four different HPV genotypes when present at 62.5 copies or less in the biological sample. Support for this amendment

is found, for example, in Example 1 of the specification.

The applicants submit that the combination of references cited by the Examiner does not teach all of the elements of the claims as required for rejection under 35 U.S.C. 103. In particular, none of the cited references, alone or in combination, teach or suggest a multiplex assay for amplification of low copy numbers of the recited genotypes of HPV.

In addition, the applicant submit that even if the references are combined (the applicants submit that the references are not properly combined), the references do not provide an expectation of success, should the combination be carried out. Jeney teaches only the PCR amplification of HPV regions, not the multiplex PCR assay of the specific genotypes of the presently claimed invention. Moreover, Jeney provides no data to assess the accuracy of the assay nor whether the assay was reliable to low copy numbers achievable with the presently claimed invention. In particular, the assay of the present application is sensitive enough to reliably amplify HPV at very low quantities (62.5 copy number).

Lowe further does not teach or suggest a method of detecting the HPV genome in a multiplex assay comprising the primers specific to the genome of HPV genotype 11, 16, 18 and 31. Lowe merely provides teaching of primer design for single amplification reactions. The cited Accession numbers simply disclose the full genome including the L1 gene sequence of HPV types 11, 16, 18, and 31. That is, they are silent on a method of designing a multiplex assay comprising the primers specific to the genome of these HPV genotypes.

Additionally, none of the cited references, alone or in combination, teach a multiplex PCR using type specific primers against one specific loci where the primer pairs are specific for different HPV types and can selectively amplify each HPV type from the same loci with a high degree of accuracy, as is achieved with the current invention. Furthermore, none of the cited references disclose an assay using L1 type specific primers in a single assay where each primer selectively and reliably amplifies a specific HPV type for low copy numbers of HPV. The presently claimed invention

therefore provides a non-obvious method that is fast and accurate and in which multiple low copy number HPV subtypes may be identified and typed in a single assay. The assay as presently claimed is far less onerous than those of the prior art and offers the further advantage that it allows quantification of HPV levels to a very low level.

The performance of the PCR methods of the presently claimed invention enables sensitive quantitative analysis of very small amounts (see Example 3 of the specification) and accurate detection of HPV genotypes (see Example 4 of the specification). Also, when PCR is carried out using the methods of the presently claimed invention, consistent results are obtained upon repeated PCR performance (see Example 5 of the specification). That is, since the methods of the presently claimed invention is highly valid and reliable, the results obtained with the present primer pairs are highly reliable.

The applicants submit that none of the cited references, alone or in combination, teach or suggest that the combination would be successful in amplifying low copy numbers of specific HPV genotypes in a multiplex assay as recited in the presently claimed invention. Accordingly, the applicants submit that the Examiner has not demonstrated a prima facie case of obviousness and respectfully submit that the rejection be withdrawn.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (608) 662-1277.

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